Calendar No. 416

106TH CONGRESS
1ST SESSION

S. 1561

A BILL

To amend the Controlled Substances Act to add gamma hydroxybutyric acid and ketamine to the schedules of control substances, to provide for a national awareness campaign, and for other purposes.

NOVEMBER 18, 1999

Reported with amendments and an amendment to the title

Calendar No. 416

106TH CONGRESS
1ST SESSION

S. 1561

To amend the Controlled Substances Act to add gamma hydroxybutyric acid and ketamine to the schedules of control substances, to provide for a national awareness campaign, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 1999

Mr. ABRAHAM (for himself, Mr. DEWINE, Mr. GRAHAM, Mrs. FEINSTEIN, Mr. GRASSLEY, Mr. LIEBERMAN, and Mr. COVERDELL) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

NOVEMBER 18, 1999

Reported by Mr. HATCH, with amendments and an amendment to the title

[Omit the part struck through and insert the part printed in italic]

A BILL

To amend the Controlled Substances Act to add gamma hydroxybutyric acid and ketamine to the schedules of control substances, to provide for a national awareness campaign, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the ''Date-Rape Drug Control Act of 1999''.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Samantha Reid and Hillory J. Farias Date-Rape Drug Prohibition Act of 1999''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Gamma hydroxybutyric acid (also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop) has become a significant and growing problem in law enforcement. At least 20 States have scheduled such drug in their drug laws and law enforcement officials have been experiencing an increased presence of the drug in driving under the influence, sexual assault, and overdose cases especially at night clubs and parties.

(2) A behavioral depressant and a hypnotic, gamma hydroxybutyric acid (''GHB'') is being used in conjunction with alcohol and other drugs with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of such drug's ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol which potentiates its impact.

(3) GHB takes the same path as alcohol, processes via alcohol dehydrogenase, and its symptoms at high levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. Thus, aggression and violence can be expected in some individuals who use such drug.

(4) If taken for human consumption, common industrial chemicals such as gamma butyrolactone and 1.4-butanediol are swiftly converted by the body into GHB. Illicit use of these and other GHB analogues and precursor chemicals is a significant and growing law enforcement problem.

(5) A human pharmaceutical formulation of gamma hydroxybutyric acid is being developed as a treatment for cataplexy, a serious and debilitating disease. Cataplexy, which causes sudden and total loss of muscle control, affects about 65 percent of the estimated 180,000 Americans with narcolepsy, a sleep disorder. People with cataplexy often are unable to work, drive a car, hold their children or live a normal life.

(6) Abuse of illicit GHB is an imminent hazard to public safety that requires immediate regulatory action under the Controlled Substances Act (21 U.S.C. 801 et seq.).

SEC. 3. ADDITION OF GAMMA HYDROXYBUTYRIC ACID AND KETAMINE TO SCHEDULES OF CONTROLLED SUBSTANCES; GAMMA BUTYROLACTONE AS ADDITIONAL LIST I CHEMICAL.

(a) ADDITION TO SCHEDULE I.—

(1) IN GENERAL.—Section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end of schedule I the following:

''(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following substance having a depressant effect on the central nervous system, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

''(1) Gamma hydroxybutyric acid.''.

(2) SECURITY OF FACILITIES.—For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, gamma hydroxybutyric acid and its salts, isomers, and salts of isomers manufactured, distributed, or possessed in accordance with an exemption approved under section 505(i) of the Federal Food, Drug, and Cosmetic Act shall be treated as a con-

trolled substance in schedule III under section 202(c) of the Controlled Substances Act.

(b) ADDITION TO SCHEDULE III.—Schedule III under section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in (b)—

(1) by redesignating (4) through (10) as (6) through (12), respectively; and

(2) by redesignating (3) as (4);

(3) by inserting after (2) the following:

"(3) Gamma hydroxybutyric acid and its salts, isomers, and salts of isomers contained in a drug product for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act."; and

(4) by inserting after (4) (as so redesignated) the following:

"(5) Ketamine and its salts, isomers, and salts of isomers.".

(c) ADDITIONAL LIST I CHEMICAL.—Section 102(34) of the Controlled Substances Act (21 U.S.C. 802(34)) is amended—

(1) by redesignating subparagraph (X) as subparagraph (Y); and

(2) by inserting after subparagraph (W) the following subparagraph:

''(X) Gamma butyrolactone.''.

(d) RULE OF CONSTRUCTION REGARDING CONTROLLED SUBSTANCE ANALOGUES.—Section 102(32) of the Controlled Substances Act (21 U.S.C. 802(32)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraph (C)'';

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following new subparagraph (B):

''(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) that the chemical is a controlled substance analogue.''.

(e) PENALTIES REGARDING SCHEDULE I.—

(1) IN GENERAL.—Section 401(b)(1)(C) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(C)) is amended in the first sentence by inserting after ''schedule I or II,'' the following: ''gamma hydroxybutyric acid in schedule III,''.

(2) CONFORMING AMENDMENT.—Section 401(b)(1)(D) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(D)) is amended by inserting

~~''(other than gamma hydroxybutyric acid)'' after ''schedule III''.~~

~~(f) DISTRIBUTION WITH INTENT TO COMMIT CRIME OF VIOLENCE.—Section 401(b)(7)(A) of the Controlled Substances Act (21 U.S.C. 841(b)(7)(A)) is amended by inserting ''or controlled substance analogue'' after ''distributing a controlled substance''.~~

SEC. 3. EMERGENCY SCHEDULING OF GAMMA HYDROXYBUTYRIC ACID AND LISTING OF GAMMA BUTYROLACTONE AS LIST I CHEMICAL.

(a) EMERGENCY SCHEDULING OF GHB.—

(1) IN GENERAL.—The Congress finds that the abuse of illicit gamma hydroxybutyric acid is an imminent hazard to the public safety. Accordingly, the Attorney General, notwithstanding sections 201(a), 201(b), 201(c), and 202 of the Controlled Substances Act, shall issue, not later than 60 days after the date of the enactment of this Act, a final order that schedules such drug (together with its salts, isomers, and salts of isomers) in the same schedule under section 202(c) of the Controlled Substances Act as would apply to a scheduling of a substance by the Attorney General under section 201(h)(1) of such Act (relating to imminent hazards to the public safety), except as follows:

(A) For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, the final order shall treat such drug, when the drug is manufactured, distributed, or possessed in accordance with an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (whether the exemption involved is authorized before, on, or after the date of the enactment of this Act), as being in the same schedule as that recommended by the Secretary of Health and Human Services for the drug when the drug is the subject of an authorized investigational new drug application (relating to such section 505(i)). The recommendation referred to in the preceding sentence is contained in the first paragraph of the letter transmitted on May 19, 1999, by such Secretary (acting through the Assistant Secretary for Health) to the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration), which letter was in response to the letter transmitted by the Attorney General (acting through such Deputy Administrator) on September 16, 1997. In publishing the final order in the Federal Register,

the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

(B) In the case of gamma hydroxybutyric acid that is contained in a drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (whether the application involved is approved before, on, or after the date of the enactment of this Act), the final order shall schedule such drug in the same schedule as that recommended by the Secretary of Health and Human Services for authorized formulations of the drug. The recommendation referred to in the preceding sentence is contained in the last sentence of the fourth paragraph of the letter referred to in subparagraph (A) with respect to May 19, 1999.

(2) FAILURE TO ISSUE ORDER.—If the final order is not issued within the period specified in paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) is deemed to be scheduled under section 202(c) of the Controlled Substances Act in accordance with the policies described in paragraph (1), as if the Attorney General

had issued a final order in accordance with such paragraph.

(b) ADDITIONAL PENALTIES RELATING TO GHB.—

(1) CONTROLLED SUBSTANCES ACT.—

(A) IN GENERAL.—Section 401(b)(1)(C) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(C)) is amended in the first sentence by inserting after "schedule I or II," the following: "gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Samantha Reid and Hillory J. Farias Date-Rape Drug Prohibition Act of 1999),".

(B) CONFORMING AMENDMENT.—Section 401(b)(1)(D) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(D)) is amended by striking ", or 30" and inserting "(other than gamma hydroxybutyric acid), or 30".

(2) CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.—

(A) IN GENERAL.—Section 1010(b)(3) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(3)) is amended in the first sentence by inserting after "I or II," the following: "gamma hydroxybutyric acid (including

when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Samantha Reid and Hillory J. Farias Date-Rape Drug Prohibition Act of 1999),".

(B) CONFORMING AMENDMENT.—Section 1010(b)(4) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(4)) is amended by striking "flunitrazepam)" and inserting the following: "flunitrazepam and except a violation involving gamma hydroxybutyric acid)".

(c) GAMMA BUTYROLACTONE AS ADDITIONAL LIST I CHEMICAL.—Section 102(34) of the Controlled Substances Act (21 U.S.C. 802(34)) is amended—

(1) by redesignating subparagraph (X) as subparagraph (Y); and

(2) by inserting after subparagraph (W) the following subparagraph:

"(X) Gamma butyrolactone.".

SEC. 4. AUTHORITY FOR ADDITIONAL REPORTING REQUIREMENTS FOR GAMMA HYDROXYBUTYRIC PRODUCTS IN SCHEDULE III.

Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended by adding at the end the following:

''(h) In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

''(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

''(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

''(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases,

including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

''(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

''(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

''(6) That section 310(b)(3) (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.''.

~~SEC. 5. DEVELOPMENT OF FORENSIC FIELD TESTS FOR GAMMA HYDROXYBUTYRIC ACID.~~

~~The Attorney General shall make a grant for the development of forensic field tests to assist law enforcement officials in detecting the presence of gamma hydroxybutyric acid and related substances.~~

SEC. 5. CONTROLLED SUBSTANCES ANALOGUES.

(a) RULE OF CONSTRUCTION REGARDING CONTROLLED SUBSTANCE ANALOGUES.—Section 102(32) of the Controlled Substances Act (21 U.S.C. 802(32)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraph (C)'';

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following new subparagraph (B):

''(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph

(34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.".

(b) DISTRIBUTION WITH INTENT TO COMMIT CRIME OF VIOLENCE.—Section 401(b)(7)(A) of the Controlled Substances Act (21 U.S.C. 841(b)(7)(A)) is amended by inserting "or controlled substance analogue" after "distributing a controlled substance".

SEC. 6. DEVELOPMENT OF MODEL PROTOCOLS, TRAINING MATERIALS, FORENSIC FIELD TESTS, AND COORDINATION MECHANISM FOR INVESTIGATIONS AND PROSECUTIONS RELATING TO GAMMA HYDROXYBUTYRIC ACID, OTHER CONTROLLED SUBSTANCES, AND DESIGNER DRUGS.

(a) IN GENERAL.— The Attorney General, in consultation with the Administrator of the Drug Enforcement Administration and the Director of the Federal Bureau of Investigation, shall—

(1) develop—

(A) model protocols for the collection of toxicology specimens and the taking of victim statements in connection with investigations into and prosecutions related to possible violations of the Controlled Substances Act or other Federal or

State laws that result in or contribute to rape, other crimes of violence, or other crimes involving abuse of gamma hydroxybutyric acid, other controlled substances, or so-called "designer drugs"; and

(B) model training materials for law enforcement personnel involved in such investigations; and

(2) make such protocols and training materials available to Federal, State, and local personnel responsible for such investigations.

(b) GRANT.—

(1) IN GENERAL.—The Attorney General shall make a grant, in such amount and to such public or private person or entity as the Attorney General considers appropriate, for the development of forensic field tests to assist law enforcement officials in detecting the presence of gamma hydroxybutyric acid and related substances.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subsection.

(c) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Attorney General shall submit to the Committees on the Judiciary of the Senate and

House of Representatives a report on current mechanisms for coordinating Federal, State, and local investigations into and prosecutions related to possible violations of the Controlled Substances Act or other Federal or State laws that result in or contribute to rape, other crimes of violence, or other crimes involving the abuse of gamma hydroxybutyric acid, other controlled substances, or so-called ''designer drugs''. The report shall also include recommendations for the improvement of such mechanisms.

~~**SEC. 6. ANNUAL REPORT REGARDING DATE-RAPE DRUGS; NATIONAL AWARENESS CAMPAIGN.**~~

SEC. 7. ANNUAL REPORT REGARDING DATE-RAPE DRUGS; NATIONAL AWARENESS CAMPAIGN.

(a) ANNUAL REPORT.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall periodically submit to Congress reports each of which provides an estimate of the number of incidents of the abuse of date-rape drugs (as defined in subsection (c)) that occurred during the most recent one-year period for which data are available. The first such report shall be submitted not later than January 15, 2000, and subsequent reports shall be submitted annually thereafter.

(b) NATIONAL AWARENESS CAMPAIGN.—

(1) DEVELOPMENT OF PLAN; RECOMMENDATIONS OF ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall develop a plan for carrying out a national campaign to educate individuals described in subparagraph (B) on the following:

(i) The dangers of date-rape drugs.

(ii) The applicability of the Controlled Substances Act to such drugs, including penalties under such Act.

(iii) Recognizing the symptoms that indicate an individual may be a victim of such drugs, including symptoms with respect to sexual assault.

(iv) Appropriately responding when an individual has such symptoms.

(B) INTENDED POPULATION.—The individuals referred to in subparagraph (A) are young adults, youths, law enforcement personnel, educators, school nurses, counselors of rape victims, and emergency room personnel in hospitals.

(C) ADVISORY COMMITTEE.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall establish an advisory committee to make recommendations to

the Secretary regarding the plan under subparagraph (A). The committee shall be composed of individuals who collectively possess expertise on the effects of date-rape drugs and on detecting and controlling the drugs.

(2) IMPLEMENTATION OF PLAN.—Not later than 180 days after the date on which the advisory committee under paragraph (1) is established, the Secretary, in consultation with the Attorney General, shall commence carrying out the national campaign under such paragraph in accordance with the plan developed under such paragraph. The campaign may be carried out directly by the Secretary and through grants and contracts.

(3) EVALUATION BY GENERAL ACCOUNTING OFFICE.—Not later than two years after the date on which the national campaign under paragraph (1) is commenced, the Comptroller General of the United States shall submit to Congress an evaluation of the effects with respect to date-rape drugs of the national campaign.

(c) DEFINITION.—For purposes of this section, the term ''date-rape drugs'' means gamma hydroxybutyric acid and its salts, isomers, and salts of isomers and such other drugs or substances as the Secretary, after consulta-

tion with the Attorney General, determines to be appropriate.

SEC. 8. SPECIAL UNIT IN DRUG ENFORCEMENT ADMINISTRATION FOR ASSESSMENT OF ABUSE AND TRAFFICKING OF GHB AND OTHER CONTROLLED SUBSTANCES AND DRUGS.

(a) ESTABLISHMENT.—Not later than 60 days after the date of the enactment of this Act, the Attorney General shall establish within the Operations Division of the Drug Enforcement Administration a special unit which shall assess the abuse of and trafficking in gamma hydroxybutyric acid, flunitrazepam, ketamine, other controlled substances, and other so-called "designer drugs" whose use has been associated with sexual assault.

(b) PARTICULAR DUTIES.—In carrying out the assessment under subsection (a), the special unit shall—

(1) examine the threat posed by the substances and drugs referred to in that subsection on a national basis and regional basis; and

(2) make recommendations to the Attorney General regarding allocations and reallocations of resources in order to address the threat.

(c) REPORT ON RECOMMENDATIONS.—

(1) REQUIREMENT.—Not later than 180 days after the date of the enactment of this Act, the Attor-

ney General shall submit to the Committees on the Judiciary of the Senate and House of Representatives a report which shall—

(A) set forth the recommendations of the special unit under subsection (b)(2): and

(B) specify the allocations and reallocations of resources that the Attorney General proposes to make in response to the recommendations.

(2) TREATMENT OF REPORT.—Nothing in paragraph (1) may be construed to prohibit the Attorney General or the Administrator of the Drug Enforcement Administration from making any reallocation of existing resources that the Attorney General or the Administrator, as the case may be, considers appropriate.

SEC. 9. TECHNICAL AMENDMENT.

Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended by redesignating subsections (d), (e), (f), and (g) as subsections (c), (d), (e), and (f), respectively.

Amend the title so as to read: ''An Act to amend the Controlled Substances Act to direct the emergency scheduling of gamma hydroxybutyric acid, to provide for a national awareness campaign, and for other purposes.''.